IN fOCUS
Topics in health care ethics
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Informed Consent
Do's and Don'ts for Best Practice

Patients have a fundamental right to direct what happens to their bodies, grounded in the principles of autonomy and respect for persons.[1] In turn, health care professionals have an ethical obligation to involve patients in a process of shared decision making and to seek patients' informed consent for treatments and procedures. Good informed consent practices, thus, are an essential component of ethics quality in health care. And that means more than getting a patient's signature on a consent form.

Informed consent is always specific

The goal of the informed consent process is to ensure that patients have an opportunity to be informed participants in decisions about their health care.[2] To achieve that goal, VA policy requires, among other things, that practitioners explain the patient's condition and diagnosis. They must inform the patient (or authorized surrogate) about treatment options and alternatives, including the risks and benefits of each, providing the information that a "reasonable person" in similar circumstances would want to know in making the treatment decision. *A key element of the process is that the practitioner explain why he or she believes recommended treatments or procedures will be more beneficial than alternatives in the context of the patient's diagnosis.*[3]

Thus informed consent is always specific: to the individual patient, the clinical situation, and the recommended plan of care or recommended treatment(s) or procedure(s).

Consent for multiple treatments

However, to say that consent is always specific is not the same as saying that separate consent is always required for every episode of repeated treatment. When the plan of care for a given diagnosis involves repeated treatments or procedures—for example, a course of chemotherapy or ongoing dialysis—practitioners should ensure the patient understands that he or she is consenting to

Do! *ask patients to give consent for recommended treatments or procedures, or a recommended plan of care, in the context of a particular diagnosis.*

Do! *follow good informed consent process:*

Explain the patient's condition and diagnosis clearly and concisely, in language he or she can understand.

Inform the patient about the treatment(s) or procedure(s) you recommend, including

- the name, nature, and details of the recommended treatment(s) or procedure(s);
- indications for the recommended course of action;
- likelihood of success of the recommended treatment(s) or procedure(s) for this patient.

Describe the expected benefits and known risks of the recommended treatement(s) or procedure(s).

Describe reasonable alternatives to the recommended treatment(s) or procedure(s), including the expected benefits and known risks of each alternative.

Identify the practitioners who will be involved in performing the treatment or procedure

Advise the patient if the recommended treatment or procedure is novel or unorthodox.

Encourage the patient to ask questions.

Do! *ensure that patients understand when their care will involve repeated treatments or procedures, such as chemotherapy or dialysis.*

Do! *document the* process *of shared decision making and oral consent in the patient's health record even when signature consent is not required.*

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Don't! *ask patients to give "blanket" or "routine" consent—e.g., for* "any treatment your doctors think is necessary" or "the use of blood products if needed for any reason during your hospital stay."

Don't! *"presume" consent. (See Handbook 1004.1 regarding special considerations that apply to consent for treatment in medical emergencies.)*

Don't! *ask patients to give consent in advance for HIV testing "in case an occupational exposure takes place."*

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multiple episodes of treatment. Separate consent is not required for each individual episode (e.g., each administration of chemotherapy or each dialysis session).[3]

"Blanket" consent is *NOT* informed consent

Informed consent for a planned course of multiple repeated treatments based on a specific diagnosis is very different from practices sometimes referred to as "routine" or "blanket" consent. Asking a patient to agree at the outset of care to "any treatment your doctors think is necessary," or "routine procedures as needed," or "the use of blood products if needed for any reason during your hospitalization" is ethically problematic in several ways.

Such practices fail to meet the requirement that consent be specific. This is the case even when common procedures are identifed. For example, asking a patient entering the ICU to consent to use of a ventilator or vasopressors, performance of thoracentesis, or other common critical care interventions, "if needed." Such individual procedures are not part of a plan of care because they are not anticipated to be clinically indicated or recommended for that individual patient at the time consent is obtained.

Moreover, seeking consent "in case" a patient should need some *future* intervention that is not related to that patient's current clinical status violates the fundamental ethical norm that patients must make decisions about proposed treatments or procedures in the context of their present situation. As a "patient-centered action," informed consent involves the patient's "*contemporaneous* bodily integrity, rights, dignity, intelligence, preferences, interests, goals, and welfare."[4]

If a patient's condition changes enough to warrant a change in the plan of care, the practitioner must explain to the patient (or authorized surrogate) how the situation has changed, establish goals of care in light of the new situation, recommend a new plan of care, and obtain informed consent for the new plan or for specific treatment(s) or procedure(s) now recommended.

Notification versus consent

Informed consent is also different from "notification," that is, providing general information relevant to patients' participation in health care. For example, among other things, patients entering VA health care facilities are *notified* that their medical condition will dictate whether they will be permitted to wear their own clothing.[5]

Similarly, every patient entering a health care facility must be notified that his or her records will be used for purposes of routine health care operations.[6] Likewise, each patient should be notified that his or her information may be used for quality improvement purposes to enable the organization to fulfill its obligation to monitor the quality of care it delivers and to carry out quality improvement activities for the benefit of all patients.[7,8]

Notification informs patients not only about their rights, but also about organizational activities and processes that shape how care is delivered. Like informed consent, notification serves the goal of respecting patients as moral agents.

References & Resources

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3. VHA Handbook 1004.1, *Informed Consent for Clinical Treatments and Procedures*.
4. Reagan JE. Ask the ethicist: Does preoperative consent include postoperative complications? *Lahey Clinic Medical Ethics* 2004;11(2):3.
5. U.S. Department of Veterans Affairs, *Patient Rights and Responsibilities*.
6. Final Privacy Rule. Health Information and Portability Accountability Act, 45 CFR 164.510(b).
7. Bailey MA, Bottrell M, Lynn J, Jennings B. The ethics of using QI methods to improve health care quality and safety. *Hastings Center Report* 2006;July-August[Special Suppl]:S1–S39.
8. JCAHO, *Comprehensive Accreditation Manual for Hospitals,* 2006. HR.1.30.